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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,519	06/22/2007	Dieter Manstein	036213/US/3 - 475387-290	1188
30873 7590 12/22/2010 DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 250 PARK AVENUE NEW YORK, NY 10177			EXAMINER BUCKLEY, AUDREA	
			ART UNIT 1617	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,519	Applicant(s) MANSTEIN, DIETER	
	Examiner AUDREA J. BUCKLEY	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11,13,16,17,20-25 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11,13,16,17,20-25 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

This action is in response to remarks and amendments filed 10/6/2010. Claims 1 and 11 were amended. Claims 27-30 are newly added. Support for the new claims is found on page 7 of the specification as filed. Accordingly, claims 1, 3-9, 11, 13, 16, 17, 20-25, and 27-30 are pending in the application.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (US 2003/0159615 A1, filed Mar. 2003).

Anderson et al. teach permanent and removable tissue markings designed in advance for change and/or removal on demand; these markings are implemented by applying specific energy such as electromagnetic radiation to the tissue marking site where colored microparticles have been implanted (see abstract, in particular).

Regarding claim 1, Anderson et al. teach that chromophores (see paragraphs [0087]-[0091]) are applied as tissue markings in the skin by implantation (see [0131], [0133], and [0136]). It is noted that this implantation process necessarily requires the

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application to a predetermined area of skin a specific pattern of fractional wounding as in the first method step of pending claim 1. Anderson et al. further teach the subsequent selective change and/or removal of these tissue marking microparticles can be applied (see [0044] and [0032]) by exposure to a specific type of electromagnetic energy (radiation) (see [0142]). Anderson et al. teach that this selective change is a pre-determined removal method which may be employed for changing or removing a tissue marking [0044]). Therefore, Anderson et al. teach the method steps of the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4, and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0159615 A1, filed Mar. 2003).

The teachings of Anderson et al. are delineated above with respect to claim 1. It is established that when a reference anticipates an invention, it necessarily renders such invention obvious as well. *Anticipation is the "epitome of Obviousness", In re Kalm*, 378 F.2d 959, 962 (CCPA 1967). The Anderson reference teaches that the inks can be implanted using a non-invasive method such as one which is well-suited to create an even tone of pigment over a relatively large body surface area (therefore, a layer) such as in the application of a removable sun tan (see [0132]).

As to claim 3, Anderson et al. teach that incomplete removal can be achieved by administering radiation to affect only a fraction of microparticles such as to reduce the color-intensity of a marking where the extent of photobleaching can be controlled by adjusting fluence per pulse and number of pulses administered (see [0158] and Example 3 [0173]). Because it is not certain that Anderson et al. employed this method of fluence adjustment and pulse number adjustment, this rejection is made using obviousness rationale. Nonetheless, one reasonably would have expected continued success from the incomplete removal as adjusted by one of ordinary skill in the art as taught by Anderson.

As to claim 4, Example 3 [0169] further teaches that the microparticulate chromophores are prepared by grinding dry powdered Rose Bengal and sifting it to obtain uniform particles of a specified size to be implanted. Because it is not apparent that Anderson et al. implemented the powder as a dry powder, this rejection is made using obviousness rationale. However, since Anderson teaches the powder and the option to implement the powder as a suspension, it would have been obvious to one of

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ordinary skill that the option that the suspension was not a necessary form for the powder implementation. Therefore, one reasonably would have had the expectation of continued success upon the implantation of the powder form of the microparticulate chromophore (i.e., Rose Bengal as taught by Anderson).

As to claims 6-9, Anderson et al. teach coating materials which include substances capable of encapsulating chromophores such as cyanoacrylate and Epo-Tek 301, an adhesive/structural glue, manufactured by Epoxy Technology, among others. Anderson et al. does not teach a particular embodiment of the invention employing Epo-Tek 301 (attachment medium, adhesive, glue); therefore, this rejection is made using obviousness rationale. Anderson et al. further teach that in some embodiments the coating is made of a material including specific absorption components that strongly absorb in a particular spectral region with the region from 800 to 1800 nm (light-activated) being most desirable [0080]). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement Epo-Tek 301, for instance, and/or a specific absorption component, in accordance with the teachings of Anderson. One would have been motivated to use Epo-Tek 301 in particular since Anderson teaches that these materials are biocompatible and approved by the FDA for use in medical devices (see [0121]), and one would have been motivated to use specific absorption (light-activated) components in order to control the release of the chromophores (see [0080]).

Claims 5, 11, 13, 16, 17, 20-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0159615 A1, filed Mar. 2003) as applied above and further in view of Mueller et al. (US 5,836,998, patented Nov. 1998).

The teachings of Anderson et al. are delineated above. Anderson et al. teach that the microparticles can be used to produce new cosmetic markings by addition to the tissue of and/or under the fingernails, for example, to create solid colors, patterns, or designs for decorative purposes [0138].

As to claims 5, 13, and 17, Anderson et al. do not teach the devices (i.e., stencil) for application as instantly recited. As to claims 11 and 16, Anderson et al. do not teach the application of a mask with a pattern where the pattern corresponds to the desired “fractional wounding” pattern.

However, Mueller et al. teach a stencil for body art wherein the stencil allows a decorative stain to be applied to a predetermined epidermal area (see column 1, line 65 – column 2, line 11). As to claims 16 and 25, see Figure 1 in which the stencil design (a heart shape) allows for the application of color (chromophore) where the skin is not in contact with the mask.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement the stencil pattern as taught by Mueller et al. for improved control of the chromophore application/removal pattern in the methods of Anderson et al. One would have been motivated to do so in order to minimize human

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error and to maximize control over the product design in its application, as taught by Mueller et al. (see column 2, lines 9-10).

As to claims 20 and 21, Anderson et al. teach chromophores including modern pigments of inorganic metal salts and brightly colored organometallic complexes [0006] which necessarily would act as chromophores, reflecting light and colors. Also, Anderson teaches silica and glass light reflectors as chromophore components Bis(diiminosuccino-nitrilo)metal complexes and silica are an example of these chromophores (see Anderson claim 35, for instance). Based on this teaching, one of ordinary skill in the art reasonably would have expected continued success from the implementation of the metal complex or silica chromophores taught by Anderson.

As to claim 22, it is noted that Anderson et al. teach graphite (carbon) and carbon among the chromophore components (see [0023]) where graphite in particular is named among the examples of useful colored near-infrared absorbing materials [0095]). Anderson's Example 1 employs graphite particles in the chromophore microparticles (see [0162]). As to claim 23, it is noted that Example 2 of Anderson teaches that yellow microparticles are ruptured by IR radiation (heat) (see [0165]). Therefore, Anderson teaches a yellow chromophore that undergoes a phase transition upon a change in temperature. As to claim 23, Anderson teaches that the chromophore may be thermolabile such that exposure of the microparticle to the specific energy heats and alters the chromophore (see [0023]). Based further on the teaching of Mueller et al, one of ordinary skill in the art at the time the invention was made would have expected

continued success upon implementing the chromophores of Anderson et al. in various embodiments of the invention.

New Grounds of Rejection

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0159615 A1, filed Mar. 2003) in view of Mueller et al. (US 5,836,998, patented Nov. 1998) as applied above, and further in view of Epstein et al. (US 2002/0091311 A1, published Jul. 2002).

The teachings of Anderson et al. and Mueller et al. are delineated above.

As to claim 24, Anderson et al. teach waxes with a melting point substantially above body temperature (i.e., paraffin), for example, natural waxes, synthetic waxes, and mixtures, (see [0079] and [0113]). However, neither Anderson et al. nor Mueller et al. teaches any paraffin in particular.

However, Epstein et al. teach methods for transporting substances across a biological membrane of an animal such as a human where openings in the biological membrane facilitate treatment applications, et cetera. Specifically, Epstein et al. teach that the substrate may be designed to deliver pigments to effect an instantaneous tattoo application upon detonation of the pyrotechnic charges suitable for veterinary or cosmetic tattoos. The substrate may preferably be chosen from the suitable examples including paraffin, waxes, and other functional equivalents (see [0002] and [0044]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize paraffin in particular as taught by Epstein et al.

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for the wax generally disclosed in Example 1 of Anderson et al. From this substitution of equivalents known for the same purpose, one of ordinary skill in the art at the time the invention was made reasonably would have expected continued success (see MPEP 2144.06) and would have been motivated to make this substitution since paraffin is a particular suitable material more specific than "wax" and explicitly taught to be useful for containing pigments for cosmetic tattoos (see [0044]).

New Grounds of Rejection as Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "of the skin" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim since claim 1 has been amended to delete the word "skin".

Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0159615 A1, filed Mar. 2003) as applied above.

The teachings of Anderson et al. are delineated above. Further regarding claim 27, Anderson et al. teach that chromophores (see paragraphs [0087]-[0091]) are

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applied as tissue markings in the skin by implantation (see [0131], [0133], and [0136]) and that the subsequent selective change and/or removal of these tissue marking microparticles can be applied (see [0044] and [0032]) by exposure to a specific type of electromagnetic energy (radiation) (see [0142]). It is noted that this implantation process necessarily requires the application to a predetermined area of skin a specific pattern of fractional wounding. Anderson et al. teach that this selective change is a predetermined removal method which may be employed for changing or removing a tissue marking [0044]). Anderson et al. explicitly teach that the inks can be implanted using a non-invasive method such as one which is well-suited to create an even tone of pigment over a relatively large body surface area such as in the application of a removable sun tan (see [0132]). Further, Anderson et al. teach that incomplete removal can be achieved by administering radiation to affect only a fraction of microparticles such as to reduce the color-intensity of a marking where the extent of photobleaching can be controlled by adjusting fluence per pulse and number of pulses administered (see [0158] and Example 3 [0173]). As to claim 27, this teaching indicates that one of ordinary skill in the art at the time of the invention would have been able to apply the tissue markings in a selected pattern (thus, simultaneously not applying tissue markings or generating a thermal injury in at least a portion of the predetermined area).

As to claims 28 and 29, Anderson et al. does not specify the exact instantly recited dimensions.

Nonetheless, the Anderson reference indicates that the microparticles (equal to or including the chromophore) have a radius between 50 nanometers and 100 microns

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(see [0027] and [0028]). Since the area of affected tissue corresponds to the contacted chromophores, the area of thermally or radiatively damaged skin would have correlated to the chromophore size. This particle size range overlaps with the approximate 1-1000 micrometer dimension range of claim 28 and the approximate 100-800 micrometer dimension range of claim 29. MPEP 2144.05 says that in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize microparticles sized as taught by Anderson and to subsequently optimize the microparticle size in order to control inflicted changes to the exposed tissue. One would have been motivated to do so since the Anderson reference teaches that exposure to the specific energy results in the controlled release of the colored microparticles (chromophores) in the pattern of chromophore deposition (see [0028]).

As to claim 30, Anderson teaches that skin injury is extremely local (see [0012]) and indicates that the light pulses are controlled with little or no absorption by surrounding tissue. Regarding the distance between damaged tissue regions as in pending claim 30, it is the Examiner's position that this spacing feature is a result effective variable which depends on the chromophore/particle pattern of distribution as applied by the artisan. That is, the spacing feature of pending claim 30 is a result effective variable because changing it will clearly affect the type of product obtained.

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See MPEP § 2144.05 (B). Case law holds that “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In view of this, it would have been obvious to one of ordinary skill in the art to utilize appropriate spacing distances between thermally damaged regions of tissue, including those within the scope of the present claim, so as to provide the desired end results of the predetermined tissue application of chromophores/particles.

Response to Arguments

Applicant's arguments presented 10/6/2010 have been fully considered but are not persuasive. As to the foreign patent documents excluded from consideration in the 4/4/08 IDS, Applicant's remarks filed 10/6/2010, page 8, indicate that additional references will be submitted. As of the date of the instant Office action, the Examiner notes that no new IDS or corresponding documents have been submitted for consideration. As noted above, all rejections previously presented and not re-iterated herein are withdrawn. Applicant's positions against cited references are summarized and responded to as follows.

Regarding the rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the Anderson reference, Applicant takes the position that a showing of anticipation and/or obviousness has not been properly established. Applicant's delineation (pages 8-11 of

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the Remarks filed 10/6/2010) of the Examiner's burden for properly establishing a case of anticipation or obviousness has been noted.

Applicant underscores that claims 1 and 11 have been amended (last paragraph, page 11 of Remarks). Applicant defines the instant invention as one which thermally damages the skin, in contrast with the teaching of Anderson in which the microparticles containing chromophores are removed by applying electromagnetic radiation without damaging the tissue. Understanding the Anderson reference as such, Applicant takes the position that the Anderson reference teaches away from a method for fractionally wounding the skin as in the instant invention. Applicant further takes the position that the secondary references of record (Mueller and Eppstein) do not cure the alleged deficiency of the Anderson reference.

In reply, Applicant's rebuttal arguments that the Anderson reference teaches away from the instant invention have been considered but are not persuasive because it is not apparent that the instantly claimed method substantively differs from the method of Anderson. Although the Anderson reference does, as Applicant points out, indicate that visible and near-IR fluences are applied and well tolerated by the skin ([0150] of Anderson), Anderson's method as a whole applies radiation which inevitably injures the skin. Anderson is teaching that this damage is minimized, local, and temporary on account of the controlled radiation exposure and that a healing process is necessary for the pigment effect changes to occur (see [0012]). Although Anderson is teaching primarily a method of removing permanent tissue markings (tattoos) and the instant invention is teaching a method for fractional wounding of bodily tissue, the Examiner

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maintains that the Anderson reference is relevant for its specific teachings as well as its suggestions to one of ordinary skill in the art at the time the invention was made; the Anderson method teaches applied energy (i.e., electromagnetic radiation) to the tissue in order to activate microparticles which are chromophores (see abstract, in particular; see also [0131], [0133], and [0136]). Because the Anderson reference relies on the application of electromagnetic radiation, the resulting tissue necessarily undergoes thermal changes where these changes are deemed to be "damaging", even though the Anderson reference indicates that minimal "damage" to the dermis is desirable.

Because claim 24 was improperly rejected in the non-final Office action of 7/6/2010, this action is non-final. Claim 24 depends from claim 23, which was not included in the statement of rejection over the Anderson reference alone; therefore, the rejection of claim 24 was improper.

Conclusion

No claims are found allowable.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/AJB/

/Richard Schnizer/
Primary Examiner, Art Unit 1635